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**DEPARTMENT OF COMMERCE**

**National Institute of Standards and Technology**

**15 CFR Part 285**

**[Docket No.: 200128-0034]**

**RIN 0693-AB67**

**National Voluntary Laboratory Accreditation Program - Amendment to the  
Procedures and Requirements to Accredite Testing and Calibration Laboratories**

**AGENCY:** National Institute of Standards and Technology, Commerce.

**ACTION:** Final rule.

**SUMMARY:** The Director of the National Institute of Standards and Technology (NIST) is issuing a final rule amending the regulations pertaining to the operation of the National Voluntary Laboratory Accreditation Program (NVLAP) and the operation of its accreditation programs. The regulations are being revised to include recognition of proficiency testing as an accreditation activity, add or revise terms, and update NVLAP mailing information, in accordance with the applicable international standard. These changes will not impact the public directly, and will only result in minor changes to NIST's internal practices.

**DATES:** This rule is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** Dana S. Leaman, Chief, National Voluntary Laboratory Accreditation Program, 100 Bureau Drive, Stop 2140, Gaithersburg, MD 20899-2140 or by sending email to [nvlap@nist.gov](mailto:nvlap@nist.gov).

**FOR FURTHER INFORMATION CONTACT:** Dana S. Leaman, Chief, NIST/NVLAP, 100 Bureau Drive, Stop 2140, Gaithersburg, MD 20899-2140, Phone: (301) 975-4016 or email: [dana.leaman@nist.gov](mailto:dana.leaman@nist.gov). Information regarding NVLAP and the accreditation process can be obtained from <http://www.nist.gov/nvlap>.

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

Title 15, part 285 of the Code of Federal Regulations sets out procedures and general requirements under which NVLAP operates as an unbiased third party to accredit both testing and calibration laboratories. The NVLAP procedures were first published in the *Federal Register* on February 25, 1976, and have been revised several times.

NVLAP currently operates in accordance with ISO/IEC 17011:2004, *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies*. The Laboratory Accreditation Programs operated by NVLAP are established based on the criteria in ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*. Revisions to ISO/IEC 17011 and ISO/IEC 17025 were published in November 2017 with a three-year implementation period. These revisions include recognition of proficiency testing as an accreditation activity, addition and/or revision of terms, and update of the NVLAP mailing information. The purpose of this amendment is to incorporate these revised requirements into the regulations.

### **II. Incorporation by Reference**

NIST Handbook 150 presents the basic procedures under which NVLAP operates, and considers the requirements contained in ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*. ISO/IEC 17025 and NIST Handbook 150 contain the general requirements that testing and calibration laboratories must meet if they wish to demonstrate that they operate an appropriate management system, are technically competent, and are able to generate technically valid results.

The provisions of NIST Handbook 150 are being incorporated by reference into 15 CFR 285.8 and 285.14, as this will substantially reduce the volume of material published in the *Federal Register* and the CFR. NIST Handbook 150 is available at no-cost at <https://nvlpubs.nist.gov/nistpubs/hb/2020/NIST.HB.150-2020.pdf>.

### **III. Regulatory analysis**

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment are unnecessary. This final rule makes minor, technical amendments in order to conform the regulations to changes that were made to the applicable international standard. These changes will not impact the public directly, and will only result in minor changes to NIST's internal practices. None of these changes will have a substantive impact beyond those already considered in previous supporting documents. For the same reasons, there is good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effective date.

### **Executive Order 12866**

This final rule was determined to be not significant for purposes of Executive Order 12866.

### **Executive Order 13132**

This final rule does not contain policies with Federalism implications as defined in Executive Order 13132.

### **Regulatory Flexibility Act**

Because prior notice and opportunity for public comment are not required for this rule by 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., do not apply.

### **Paperwork Reduction Act**

This final rule contains no new collection of information subject to the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

### **National Environmental Policy Act**

This final rule will not significantly affect the quality of the human environment. Therefore, an environmental assessment or Environmental Impact Statement is not required to be prepared under the National Environmental Policy Act of 1969.

### **List of Subjects in 15 CFR Part 285**

Accreditation, Business and industry, Calibration, Commerce, Conformity assessment, Incorporation by reference, Laboratories, Measurement standards, Testing.

For the reasons stated in the preamble, NIST amends 15 CFR part 285 as follows:

### **PART 285—NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM**

1. The authority citation for 15 CFR part 285 continues to read as follows:

**Authority:** 15 U.S.C. 272 *et seq.*

2. Revise § 285.1 to read as follows:

### **§ 285.1 Purpose.**

The purpose of this part is to set out procedures and general requirements under which the National Voluntary Laboratory Accreditation Program (NVLAP) operates as an unbiased third party to accredit both testing and calibration laboratories. Supplementary technical and administrative requirements are provided in supporting handbooks and documents as needed, depending on the criteria established for specific Laboratory Accreditation Programs (LAPs).

3. Revise § 285.6 to read as follows:

### **§ 285.6 Application for accreditation.**

A laboratory may apply for accreditation in any of the established LAPs. The applicant laboratory shall provide a completed application to NVLAP, pay all required fees and agree to certain conditions as set forth in the NVLAP Application for Accreditation, and provide management system documentation to NVLAP (or a designated NVLAP assessor) prior to the assessment process.

### **§ 285.7 [Amended]**

4. In § 285.7, remove the word “deficiencies” wherever it occurs and add in its place the word “nonconformities.”

5. Revise § 285.8 to read as follows:

### **§ 285.8 Proficiency testing.**

(a) *Proficiency testing requirements.* Proficiency testing undertaken to meet the criteria for NVLAP accreditation shall be consistent with the provisions contained in NIST Handbook 150, *NVLAP Procedures and General Requirements* (incorporated by reference, see § 285.16), where applicable, including revisions from time to time. Laboratories must

participate in proficiency testing as specified for each LAP in the NVLAP program handbooks.

(b) *Analysis and reporting.* Proficiency testing results are analyzed by NVLAP and results of the analysis are made known to the participants. Any result not meeting the criteria specified in the NVLAP LAP program handbook is identified as a nonconformity.

(c) *Proficiency testing nonconformities.* (1) Unsatisfactory participation in any proficiency testing program is a technical nonconformity which must be resolved in order to obtain initial accreditation or maintain accreditation.

(2) Proficiency testing nonconformities are defined as, but not limited to, one or more of the following:

(i) Failure to meet specified proficiency testing performance requirements prescribed by NVLAP;

(ii) Failure to participate in a regularly scheduled “round” of proficiency testing for which the laboratory has received instructions and/or materials;

(iii) Failure to submit laboratory control data as required; or

(iv) Failure to produce acceptable test or calibration results when using NIST Standard Reference Materials or special artifacts whose properties are well-characterized and known to NIST/NVLAP.

(3) NVLAP will notify the laboratory of proficiency testing nonconformities and actions to be taken to resolve the nonconformities. Denial or suspension of accreditation will result from failure to resolve nonconformities.

6. Revise § 285.10(b) to read as follows:

**§ 285.10 Renewal of accreditation.**

\* \* \* \* \*

(b) On-site assessments of currently accredited laboratories are performed in accordance with the procedures in §285.7. If nonconformities are found during the assessment of an accredited laboratory, the laboratory must follow the procedures set forth in §285.7(e)(2) or face possible suspension or revocation of accreditation.

7. Revise § 285.12 to read as follows:

**§ 285.12 Monitoring visits.**

(a) In addition to regularly scheduled assessments, monitoring visits may be conducted by NVLAP at any time during the accreditation period. They may occur for cause or on a random selection basis. While most monitoring visits will be scheduled in advance with the laboratory, NVLAP may conduct unannounced monitoring visits.

(b) The scope of a monitoring visit may range from checking a few designated items to a complete review. The assessors may review nonconformity resolutions, verify reported changes in the laboratory's personnel, facilities or operations, or evaluate proficiency testing activities, when appropriate.

8. Revise § 285.14 to read as follows:

**§ 285.14 Criteria for accreditation.**

The requirements for laboratories to be recognized by the National Voluntary Laboratory Accreditation Program as competent to carry out tests and/or calibrations are contained in NIST Handbook 150, *NVLAP Procedures and General Requirements* (incorporated by reference, see § 285.16).

9. Revise § 285.15(b) to read as follows:

**§ 285.15 Obtaining documents.**

\* \* \* \* \*

(b) Copies of all ISO/IEC documents are available for purchase from the American National Standards Institute's eStandards Store at <http://webstore.ansi.org>. You may inspect copies of all applicable ISO/IEC documents at the National Voluntary Laboratory Accreditation Program, National Institute of Standards and Technology, 100 Bureau Drive, Room B119, Gaithersburg, MD. For access to the NIST campus, please contact NVLAP by phone at 301-975-4016 or by e-mail at [NVLAP@nist.gov](mailto:NVLAP@nist.gov) to obtain instructions for visitor registration.

10. Add § 285.16 to read as follows:

**§ 285.16 Incorporation by reference.**

Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at National Institute of Standards and Technology, National Voluntary Laboratory Accreditation Program (NVLAP), National Institute of Standards and Technology, 100 Bureau Drive, Room B119, Gaithersburg, MD. and is available from the source(s) listed in the following paragraph(s). It is also available for inspection at the National Archives and Records Administration (NARA). For access to the NIST campus, please contact NVLAP by phone at 301-975-4016 or by e-mail at [NVLAP@nist.gov](mailto:NVLAP@nist.gov) to obtain instructions for visitor registration. For information on the availability of this material at NARA, email [fedreg.legal@nara.gov](mailto:fedreg.legal@nara.gov) or go to [www.archives.gov/federal-register/cfr/ibr-locations.html](http://www.archives.gov/federal-register/cfr/ibr-locations.html).



(a) National Institute of Standards and Technology (NIST), U.S. Department of Commerce, 100 Bureau Drive, Room B119, Gaithersburg, MD, 301–975–4016  
NVLAP@nist.gov, [www.nist.gov/publications/](http://www.nist.gov/publications/).

(1) NIST Handbook 150, *National Voluntary Laboratory Accreditation Program Procedures (NVLAP) and General Requirements*, authored by Dana S. Leaman and Bethany Hackett, 2020 Edition, August 2020, 2020 (*NVLAP Procedures and General Requirements*) <https://nvlpubs.nist.gov/nistpubs/hb/2020/NIST.HB.150-2020.pdf>; into §§ 285.8(a) and § 285.14.

(2) [Reserved]

(b) [Reserved]

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Chief of Staff

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